

## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Exercise Virginia 22313-1450 www.uspto.gov

APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 09/680,946 01/22/2001 Francois Mallet 028662.96 1475 25944 7590 06/17/2003 OLIFF & BERRIDGE, PLC EXAMINER P.O. BOX 19928 FREDMAN, JEFFREY NORMAN ALEXANDRIA, VA 22320 ART UNIT PAPER NUMBER 1634

DATE MAILED: 06/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)
	09/680,946	MALLET ET AL.
	Examiner	Art Unit
	Jeffrey Fredman	1634
The MAILING DATE of this communication appears on the cover sheet with the correspondence address		
THE REPLY FILED 13 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.		
PERIOD FOR REPLY [check either a) or b)]		
<ul> <li>The period for reply expires 6 months from the mailing date of the final rejection.</li> <li>The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.         ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).</li> <li>Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee</li> </ul>		
nave been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
1. A Notice of Appeal was filed on Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.		
2. The proposed amendment(s) will not be entered because:		
(a) ☑ they raise new issues that would require further consideration and/or search (see NOTE below);		
(b) ☐ they raise the issue of new matter (see Note below);		
(c) ☑ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or		
(d) $\square$ they present additional claims without canceling a corresponding number of finally rejected claims.		
NOTE: <u>See Continuation Sheet</u> .		
3. Applicant's reply has overcome the following rejection(s): See Continuation Sheet.		
4. Newly proposed or amended claim(s) would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).		
5.⊠ The a) affidavit, b) exhibit, or c) request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.		
6. The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.		
7.⊠ For purposes of Appeal, the proposed amendment(s) a)⊠ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.		
The status of the claim(s) is (or will be) as follows:		
Claim(s) allowed: Claim(s) objected to:		
Claim(s) objected to: Claim(s) rejected: <u>1-34</u> .		
Claim(s) rejected. 1-34.  Claim(s) withdrawn from consideration:		
B. ☐ The proposed drawing correction filed on is a) ☐ approved or b) ☐ disapproved by the Examiner.		
0. Other:		Jeffrey Fredman Primary Examiner
Potent and Trademark Office		Art Unit: 1634

## Continuation Sheet (PTO-303) 009/680,946

Application No.

Continuation of 2. NOTE: The new limitations of "after step a) and maintaining the container closed until the obtainment of the desired amount of amplified product" and "wherein after step a) all steps are performed in the closed container, without subsequent addition of any ingredients" would require further search and consideration. The claims previously lacked any limitations which required the containers to be closed or which limited the addition of ingredients to the reaction mixture. Consequently, a further search is required to address these new limitations.

Continuation of 3. Applicant's reply has overcome the following rejection(s): In view of the terminal disclaimer, the double patenting rejection is withdrawn.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant argues that the reissue broadening date should be from the date of issuance of U.S. Patent 5,817,465 and not 5,654,143, since the request was filed within two years of the later issued patent. This argument is not found persuasive because the statutory section 35 U.S.C. 251, refers to the "original patent". Here, the original patent is 5,654,143, which is the "original patent" that contains the claimed subject matter. Any other result would defeat the purpose of the statute.

Applicant then argues that the Sellner rejection should be withdrawn because Sellner does not teach a method in which the sample is heated to a temperature not to exceed 75C without ACTIVATING the enzyme system having reverse transcriptase activity. Applicant here simply misstates the claim. Claim 1 states that the heating is performed without "INactivating" the enzyme system, ie that the enzyme system is functional after heating. It is clear in Sellner that the 42 C heating does not inactivate, and in fact permits, AMV reverse transcriptase activity. Further, since the claim does not require complete denaturation, it is clear that at 42 C the RNA will be partially denatured. Consequently, Applicant's argument is not consonant with the claim.

Applicant then argues that Sellner does not teach the step where "inactivation" occurs. However, here Applicant is reading limitations into the claims. Any increased temperature will cause increased denaturation of the RNA and DNA in the sample. Consequently, Sellner, in placing the nucleic acids at 42 C causes increased denaturation and meets the limitations of the claims. Applicant's attempt to read a new limitation into the claim regarding the denaturation is not found persuasive since there is no limitation on the order of the steps. The claim does not require that steps B and C not be performed simultaneously. So Sellner does not teach away from the claimed invention, but rather, anticipates the claimed invention as it is broadly claimed. Consequently, Applicant's argument is not found persuasive because it is not based in the actual limitations of the claims

Applicant then argues that Sellner does not teach the use of a 2 to 4 ratio of RT to DNA polymerase. However, Applicant fails to appreciate that Sellner is cited as a 102 rejection, not a 103 rejection. Consequently, the issue is not whether Sellner teaches away, since that is a 103 issue, but rather does Sellner perform the experiment or not. Sellner performed the experiment with the ratio of 2 to 4 RT to DNA polymerase. Sellner finds that this ratio is less effective, and on that point Applicant is correct. However, Sellner's publication constitutes a public use and public description in a printed publication of the ratio in the method. As MPEP 2131.05 notes "A reference is no less anticipatory if, after disclosing the invention, the reference then disparages it. The question whether a reference "teaches away" from the invention is inapplicable to an anticipation analysis."

Applicant then argues the Myers reference, arguing that Myers does not teach addition without subsequent addition of any ingredients. This argument is based upon the amendment submitted after final. Because the amendment was not entered, this argument is not found persuasive.

Applicant then argues that Shimomaye does not overcome the deficiencies in Sellner. Because Sellner is maintained for the reasons given above, the 103 rejection in which Shimomaye is used to teach specific features lacking in Sellner is maintained..